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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIDENTIALITY NO.
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EXAMINER

ZHOU, SHUBO

ART UNIT

PAPER NUMBER

3632

DATE MAILED: 03/26/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/493,401

Applicant(s)

MARCOTTE ET AL.

Examiner

Shubo "Joe" Zhou

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 15 July 2002 and 03 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 3-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 3-27 is/are rejected.
- 7) ☐ Claim(s) 9 and 19 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment and request for reconsideration in Paper #17, filed on 7/15/02, and in Paper #23, filed on 12/3/02, are acknowledged and the amendments entered.

Applicant's arguments in response to the previous Office Action, mailed 3/15/01, have been fully considered. Rejections and/or objections from the previous Office action not reiterated herein are hereby withdrawn. The following rejections and/or objections are either reiterated from the previous Office actions, or newly applied, and constitute the complete set presently being applied to the instant application.

Specification

The specification is objected to because of the following:

Blanks are noted on page 1, lines 12 and 14.

Appropriate correction is required.

Claim Objections

Claims 9 and 19 are objected to under 37 CFR 1.75 as being a substantial duplicate of claim 3. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claims 3 and 19 are the same. The apparent difference between claims 3 and 9 appears to be in step (a)(iii), wherein claim 3 requires "the amino acid sequence segments from

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the first and the second protein do not align to each other with any significant sequence similarity". while claim 9 requires that the first and second protein are not homologous. While the wording is slightly different, they both mean that the sequences between the two proteins do not share significant homology.

Claim Rejections-35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for reasonably determining functional links between certain proteins from a genome by establishing their phylogenetic profiles though finding homologs in additional genomes, does not reasonably provide enablement for determining functional links between a great number other proteins from a genome by establishing their phylogenetic profiles though finding homologs in additional genomes. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The claims are drawn to identifying functional links for any proteins from a genome partly based on their phylogenetic profiles in additional genomes, which are determined based on their presence or absence of homologs in the additional genomes. See also Fig. 3. While for certain proteins, for example the flagellar proteins shown in the specification (pages 32-33), the

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specification enables a skilled person in the art to use the claimed method. However, there are embodiments within the scope of the claims that appear to be inoperative. For instance, for proteins including those that are evolutionarily highly conserved, e.g. actin and glucose-6-p, this method is inoperative because the method would find them having homologs in many genomes, and conclude that they are functionally linked. Yet, obviously the conclusion would be false in the cases of actin and glucose-6-p.

The claims appear to read on significant numbers of inoperative embodiments including known house keeping proteins due to reasons as set forth above. However, since the specification does not clearly identify the operative embodiments, nor provides guidelines as to identifying the operative embodiments, undue experimentation is involved in determining those that are operative. See *Atlas Powder Co. v. E.E. duPont de Nemours & Co.*, 750 F.2d 1569, 1577, 224 USPQ 409, 414 (Fed. Cir. 1984); *In re Cook*, 439 F.2d 730, 735, 169 USPQ 298, 302 (CCPA 1971).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-27 are rejected under 35 U.S.C. 112 , second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase of "non-homologous proteins" in independent claims 3, 9 and 19, and in all their dependent claims, is vague and indefinite. It is unclear what is meant by "non-homologous proteins". Do "non-homologous proteins" mean that there is no homology between the proteins

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at the level of primary sequences? If so, what is the standard for measuring homology? What percentage of sequence homology is considered as homologous? Absent clear definition in the specification, proteins with any percentage of sequence homology can be considered as being homologous. If so, then what is "non-homologous protein"? Claims 4-8 are rejected due to their dependency from claim 4 and thus contain the limitation. Similarly, claims 10-18 are rejected due to their dependency from claim 9, and claims 20-27 are rejected due to their dependency from claim 19.

The phrase "high confidence" in independent claims 3, 9 and 19, and in all their dependent claims, is vague and indefinite. Absent a clear definition in the specification, it is unclear how high a confidence and in what measure is considered "high confidence" for identifying a functional link between two proteins.

The phrase "substantially all protein sequences" of a genome in independent claims 3, 9 and 19, and in all their dependent claims, is vague and indefinite. Absent a clear definition in the specification, it is unclear how many protein sequences encoded by a genome are considered as "substantially all" protein sequences.

The phrase "the genome" in line 1 of claim 4 lacks clear antecedent basis. There are at least two genomes recited in claim 3, from which claim 4 depends, "a first genome" and "one or more additional genomes". It is not clear which genome of the multiple genomes is meant in claim 4. Further, the last two steps of claim 4 lack clear connection with the steps of claim 3, from which claim 4 depends.

Claims 5-6 are rejected due to their dependency from claim 4 and thus containing the limitation.

Provisional Obviousness Double-Patenting Rejection

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The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 3, and 7-27 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of US patent 6,466,874 and claims 2-8, 11-21, 30-32, 34-42 of copending Application No. 09/493,498. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Claims 1-19 of US patent 6,466,874 are directed to methods of identifying proteins that are functional linked based on a method referred to as "rosetta stone" method; claims 2-8, 11-21, 30-32, 34-42 of copending Application No. 09/493,498 are directed to methods of identifying proteins that are functional linked based on a method referred to as "phylogenetic profile" method; and claims 3, and 7-27 are directed to methods of identifying proteins that are functional linked based on a method that precisely combines the method of "rosetta stone" and the method of "phylogenetic profile". While the conflicting claims are not identical, they are not patentably distinct from each.

The court has long established the following:

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"It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose....[T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted). See also *In re Crockett*, 279 F.2d 274, 126 USPQ 186 (CCPA 1960). In the instant case, the rosetta stone method of US patent 6,466,874 and the "phylogenetic profile" method of copending Application No. 09/493,498 are for the same purpose as disclosed in the specifications of US patent 6,466,874, copending Application No. 09/493,498, and the instant application: identifying proteins that are functionally linked. Thus, it would have been obvious to employ these methods in combination for their known functions/purposes.

This is a provisional obviousness-type double patenting rejection because the conflicting claims of copending Application No. 09/493,498 have not in fact been patented.

Claims 4-6 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of US patent 6,466,874 and claims 2-8, 11-21, 30-32, 34-42 of copending Application No. 09/493,498 in view of Eisen et al. (IDS document: Proc. Natl. Acad. Sci. USA, 95, 14863-8, 1998).

Claims 4-6 of the instant application are directed to methods of identifying proteins that are functionally linked based on a method that combines the procedures of the "rosetta stone" method, the "phylogenetic profile" method and the procedures of a method based on expression profile. While the combination of inventions of claims 1-19 of US patent 6,466,874 and the inventions of claims 2-8, 11-21, 30-32, 34-42 of copending Application No. 09/493,498 does not

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teach the additional procedures of expression profile, identifying proteins that are functionally linked based on expression profile would be known in the art as an equivalent for the same purpose.

Eisen et al. disclose a method of analyzing the expression profile of a number of genes encoding proteins and groups genes with similar profiles by cluster analysis. See Abstract and Figure 1 on page 14865 and Figure 2 on page 14867. Eisen et al. state that genes of similar function cluster together. See page 14865, right column.

As set forth above, it would have been obvious to employ these methods of the "rosetta stone", the "phylogenetic profile" and the expression profile in combination for their known functions/purposes.

This is a provisional obviousness-type double patenting rejection because the conflicting claims of copending Application No. 09/493,498 have not in fact been patented.

Conclusion

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to:
Shubo "Joe" Zhou, Ph.D., whose telephone number is (703) 605-1158. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst Tina Plunkett whose telephone number is (703)-305-3524, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

S. "Joe" Zhou, Ph.D.



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